GUIDELINES ON

EFFICACY DATA FOR THE REGISTRATION OF PESTICIDES FOR PLANT PROTECTION

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

COMMUNITY HEALTH CEL
47/1 [illegible] Road, Bangal[illegible] 0001

FOR THE REGISTRATION OF PESTICIDES

FOR PLANT PROTECTION

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

Rome - March 1985

1001
AGR 130
COMMUNITY HEALTH CELL
47/1, First Floor, St. Marks Road,
Bangalore - 560 001.

CONTENTS

		Page
1.	INTRODUCTION	1
	1.1 Efficacy Evaluation	1
	1.2 Comparison with Reference Products	1
	1.3 Elements in Efficacy Evaluation	1
2.	THE ROLE OF EFFICACY TESTING IN REGISTRATION	2
3.	GENERAL REQUIREMENTS FOR THE DESIGN OF THE EFFICACY TRIALS PROGRAMME	3
4.	GUIDANCE FOR DESIGNING AND REPORTING INDIVIDUAL EFFICACY TRIALS	4
	4.1 Background and Design of Individual Trials	4
	4.1.1 The Selection of Trial Sites	4
	4.1.1.1 Field Trials	4
	4.1.1.2 Trials on Glasshouse Crops	5
	4.1.2 Biology of Pests, Diseases and Weeds	5
	4.1.3 Lay-out of Individual Trials	5
	4.1.4 Choice of Reference Product	6
	4.1.5 Plot Size and Shape	6
	4.1.6 Number of Applications	6
	4.1.7 Application of the Pesticides	6
	4.1.8 Meteorological Data	7
	4.1.9 Assessment of Efficacy	7
	4.1.10 Assessment of Phytotoxicity and Other Side Effects	7
	4.1.11 Statistical Analysis of Data	7
	4.2 Report of the Experiment	7
	4.2.1 General Remarks	7
	4.2.2 Lay-out of the Report	8
REFERENCES		9
APPENDIX I:	NEED FOR INTERNATIONAL HARMONIZATION IN EFFICACY EVALUATION PROCEDURES AND METHODS	10
APPENDIX II:	EPPO GUIDELINES FOR THE BIOLOGICAL EVALUATION OF PESTICIDES	14

1. INTRODUCTION

1.1 Efficacy Evaluation

The pests, diseases and weeds of major food crops continue to be controlled by the use of chemical pesticides which offer, in many cases, the only satisfactory method of limiting losses at the present time. Thus registration authorities have to assess the efficacy and crop safety of new pesticides in order to evaluate the benefits to be obtained from their use. These benefits have to be weighed against the potential hazards from the introduction of a new compound, the decision on granting registration incorporating this benefit/risk analysis. The same indeed applies to the efficacy of pesticides used in animal husbandry and there is a need for guidelines, similar to those in this document, in that area also.

Efficacy is the ability of a pesticide to fulfil the claims made for it on the (proposed) label. It may be expressed in terms of the extent of decrease of a pest population occurring on the crop or the extent of development of the pest population surviving the treatment, and also in terms of the protection of the yield, quantity and/or quality, against damage caused directly or indirectly by the pest organism concerned. A list of the elements to be considered in efficacy evaluation is set out below.

The term "efficacy evaluation" as used here covers the evaluation of pesticides for efficacy and safety to crops, and thus is synonymous with the commonly used term "biological evaluation". The equivalent French expression "évaluation de l'efficacité is considered to have only a more specific meaning, so that the expression "évaluation biologique" is maintained as the French translation of "efficacy evaluation".

1.2 Comparison with Reference Products

In view of the variability of conditions under which pesticides are used, it is necessary to include a reference product in field trials to allow meaningful evaluation of efficacy under the conditions of the trial. Satisfactory levels of efficacy will generally be met when performance is comparable to that of such a reference product, which should preferably be a registered product widely accepted as satisfactory in practice. However, other considerations may arise in assessing what is a satisfactory level of efficacy (manner of use, side effects, etc. - see points 1.3 (h) and (i) below).

In particular, the level of control which has to be achieved by the reference product will depend on local constraints which may vary greatly (for example, from temperate to tropical countries).

Where the type of pesticide product or its use is new, comparison with a reference product may be impossible or inappropriate. In this case, the product under study should show a consistent well-defined benefit to the user. The pesticide to be introduced should be able to bring and/or keep the pest population and the damage to which it gives rise below an economic or phyto-sanitary threshold level, where this is known.

1.3 Elements in Efficacy Evaluation

The evaluation of efficacy is normally based on consideration of the following elements, as appropriate:

(a) the effect on the pest organism;

(b) the reliability, duration and consistency of protection or other intended effect(s), appropriate to the desired crop protection objective at the various development stages of the pest and/or of the crop;

(c) the effects on quantity or quality of the yield of treated plants or plant products;

(d) safety considerations, to the crop (including different cultivars), to animals or to the substrate to be treated;

(e) comparison with reference product or normally accepted practice;

(f) the compatibility with different cultural practices and other crop protection measures under the conditions of use envisaged;

(g) the effect of variables, such as climate, temperature, humidity, soil, etc. and, in the case of baits, acceptability by the pest organism;

(h) advantages of the product or its manner of use which may compensate for any deficiencies in level, duration or consistency of protection or other intended effects;

(i) undesirable or unintended side effects, e.g. on beneficial and other non-target organisms, on succeeding crops, other plants or other parts of treated plants used for propagating purposes (seeds, cuttings, runners).

2. THE ROLE OF EFFICACY TESTING IN REGISTRATION

The role of efficacy testing in the registration process is to enable the registration authority to assess the benefits of the product. In order to achieve this, it is necessary to carry out field trials under practical conditions of use. The test procedure, the design of the experiments, and the reference product should, when feasible, be discussed with registration authority.

In practice, efficacy is tested on one or several specific host/pest combinations, for each of which registration is sought. Registration authorities may find it necessary to limit their consideration to certain 'key' pests, in which case registration for so-called 'minor uses' may need to be based on efficacy data from similar uses or from other countries.

The registration authority should primarily base the efficacy evaluation on the data in the dossier submitted by the applicant. In accordance with the recommendations of the two FAO Government Consultations on International Harmonization of Pesticide Registration Requirements (1) (3) and the conclusions of the EPPO Symposium 1982 on the Harmonization of Pesticide Efficacy Evaluation (2), not only data obtained in the country concerned should be required and considered, but also relevant data obtained in other countries should be taken into account and accepted as a part of the efficacy evaluation dossier, provided those data were obtained by internationally recognized, harmonized evaluation methods.

The need for international harmonization in efficacy evaluation procedures and methods has been repeatedly stressed by international meetings (Appendix I).

When resources permit, it can be advantageous for the registration authority either to organize limited additional trials or to participate in such trials organized by the applicant. In such cases, the applicant will need to specify fully the conditions in which the trials are to be carried out, consistent with the proposed use of a product and the claims made for it.

An advantage of the active participation of the experts of the agency in the efficacy evaluation is that they become more familiar with the pesticide under study than would be possible from written reports alone. If the results obtained from these additional trials support the predictions derived from the manufacturer's data they can be regarded as a validation under the conditions of the trials. Data from independent sources should also be accepted as a part of the efficacy evaluation dossier, again provided that these data were obtained with recognized harmonized methods. In any case, the data base should be sufficient to enable the competent authorities to evaluate the product's efficacy (including crop safety) and, in particular, to determine whether the level of efficacy is satisfactory.

3. GENERAL REQUIREMENTS FOR THE DESIGN OF THE EFFICACY TRIALS PROGRAMME 1/

Only basic requirements of a general nature can be given. The design of any experiment, the required plot size and the methods for the evaluation have to be adapted to the specific pest/crop combination and the agricultural practices concerned. More detailed information on this can be found in specific internationally or nationally accepted guidelines, and as detailed in the References and in Appendix II.

It may be stressed that available guidelines relate principally to temperate crops and that, in conformity with the recommendations of the FAO Government Consultation, programmes are needed for the preparation of guidelines for the efficacy evaluation of pesticides for the control of pests of the major tropical and sub-tropical crops.

Trials are, in principal, carried out in the field. However, if the test product is to be used on a glasshouse crop, the trials are carried out under glasshouse conditions close to those of practical use.

The test programme and the documentation should be sufficiently comprehensive to allow a thorough evaluation of the efficacy of a plant protection product under study. The trials in this programme should be designed, the pesticide concerned applied, and results evaluated in such a way that a reliable judgement can be made on the efficacy of the pesticide under the conditions prevailing in these experiments.

The test programme should not only include the application of the pesticide in a typical or an "average" condition prevailing in regions in which the use is intended, but the performance of the pesticide should be studied in a range of conditions prevailing in these regions during the periods of the year the pesticide will be used.

Such programmes, including a range of conditions, will enable the evaluation of possible differences in performance of the pesticide applied under various conditions. These differences can arise from variations in climate, agricultural practices, crops and cultivars of crops grown or pests and strains of pests that occur. The test programme for a pesticide under study should always include supervised trials on main cultivars currently grown in regions where the use of the product is intended. Where relevant, the crop safety should be investigated at rates of application higher than recommended, as well as at the recommended rates.

The number of sites in which supervised trials should be carried out with a pesticide used on a specific pest/crop combination, for which an authorization is requested, is dependent on the extent of variations as mentioned above (which should be covered) and on the predictability of the occurrence of the pest or disease.

1/ See also Chapter VII, "Guidance on Efficacy Data" of the booklet "Pesticides" published by the Council of Europe (4).

As a general rule, replicated trials on annual crops should be carried out at a minimum of 8 to 10 sites in any one season. Owing to the difficulty of acquiring adequate sites in large perennial crops such as fruits, the number of sites may have to be confined to 3-5.

Where a pest is not generally abundant or the distribution of the pest population is rather uneven, a larger number of sites may be advantageous. With soil-applied chemicals, it is essential to spread the experiments over a range of soil types. This is particularly important if the pesticide may be used on rather "extreme" soil types, e.g. soils with a high organic matter content such as peat soils or very light sandy soil types. If there is any likelihood of use on such soils they should be included in the test programme.

In order to cover to some extent the variation in climatic conditions in different years, the test programme should normally be carried out in at least two successive years.

4. GUIDANCE FOR DESIGNING AND REPORTING INDIVIDUAL EFFICACY TRIALS

4.1 Background and Design of Individual Trials

4.1.1 The selection of trial sites

4.1.1.1 Field Trials

Great care is needed in the selection of test sites. The sites should be as level and uniform as possible and representative of the conditions where commercial use is anticipated. Sites with irregular soil conditions should be avoided. The pest, disease or weed which forms the object of the efficacy test should occur in a uniform pattern over the site or should be expected to become uniformly present during the trial period. With soil insects or nematodes in particular, estimates of numbers present and uniformity should be made before the start of the trial. Special conditions may favour the development of particular target pests or diseases.

When selecting a site, the preceding crop situation should be known and taken into account: A single preceding crop, on which only uniform treatments were applied, should have been grown over the whole area of the site.

Sites at field edges, or near ditches, trees, hedges or other obstacles should, in general, be avoided, as they are subject to interfering "edge" effects from those obstacles. Edge effects may however sometimes be exploited especially when the pest organism concerned prefers the field-edges rather than the middle of the field, but the trial lay-out should then be specially designed for this situation.

It is usually desirable to site the experiment towards the centre of a normal commercial crop. If this crop has to be treated with a pesticide which may interfere with those under study in the experiment, then a sufficient margin of untreated crop should be left in the immediate vicinity of the experiment. If the trial consists of repeated blocks which follow each other in the direction of drilling, spraying or other treatment of the crop, it may be helpful to have a gap between the blocks to allow for turning the supply of the pesticide on and off and for lining up the apparatus with the next plot or sub-plot.

4.1.1.2 Trials on glasshouse crops

In the glasshouse, the same general principles apply. If products with high vapour pressure, fumigants, aerosols or fogs are tested, separate glasshouses or glasshouse compartments should be used for each treatment.

4.1.2 Biology of pests, diseases and weeds

Experiments for efficacy testing of pesticide products should be designed and treated, taking into account adequate knowledge of the life history and behaviour of the pest, disease or weeds to be controlled. The timings and the mode of application of the plant protection chemical should be determined by the behaviour of the organism in question. Also the mode of action of the pesticide may influence the timing and methods of application. The evaluation methods may need to be adapted to the mode of action of the pesticide under study. Especially when a pesticide may show "delayed" effects, the observations and assessments should be designed to reveal such effects. It is also important that the experimental crop should be sown and treated similarly to a commercially grown crop, e.g. late sowings or excessively sheltered sites should be avoided since such conditions may be quite atypical and not representative for prevailing growing conditions.

4.1.3 Lay-out of individual trials

The design of a trial intended for efficacy evaluation should permit a statistical evaluation. The design, however, should not be made any more complicated than is compatible with the immediate object of the test. Multi-factorial designs should in general be avoided.

Usually a randomized block design is adequate, comprising in each block the pest control chemical(s) to be evaluated, the reference product(s) and in general a non-treated block, distributed at random in the block, the blocks being repeated as many times as there are replications (in most cases 4-5).

If it is necessary to introduce into the experiment other factors in addition to the treatments of the pesticide(s) under study at the recommended dosage rate, e.g. various times of application or other dosage rates, this can be accomplished by splitting the main plots into sub-plots, provided that the size of the sub-plots is still sufficient to allow a reliable evaluation.

Although in many cases the inclusion of non-treated control plots is essential, it has to be recognized that in some particular situations the lay-out of non-treated plots within the randomized blocks may give rise to disadvantages due to extensive interference between non-treated and treated plots. Examples are efficacy trials for fungicides with a so-called "preventive" action on susceptible cultivars of potatoes or apples aiming to control late blight and apple scab, respectively.

It may sometimes be necessary, in order to avoid heavy loss in crop growth on the trial plots or in the next year's crop, to discard the non-treated plots from the experiment shortly after the occurrence of the pest or the disease becomes obvious. The initial non-treated plots are then sprayed, taking due care to avoid drift into treated plots.

In the case of herbicide trials, efficacy tests (on weed control) and selectivity tests (for crop safety) should be considered on a separate but equal footing. In particular, for selectivity evaluation, it is desirable to test at least one dosage rate higher than the recommended rate, and to use land which is as free from weeds as possible.

4.1.4 Choice of reference product

Wherever feasible the reference product chosen should be one which has shown satisfactory results in practice; its mode of action should be the same as or similar to that of the test product.

4.1.5 Plot size and shape

No general rules can be given on the most suitable plot size; this depends on the particular combination of crop, pest or disease situation.

In orchard trials or trials on similar tree crops, it is desirable to have 4-6 trees per net plot to allow for variability between trees. In agricultural crops the minimum plot size will probably be between $10m^2$ (e.g. 5 x 2m) and $100m^2$ (e.g. 10 x 10m). The minimum plot size in very uniform vegetable or flower crops may be smaller but only in cases where internal interferences can be avoided.

The mobility of pests and lateral spread of treatments may considerably influence the plot size. Also the available apparatus for spraying or other mode of treatment and for harvesting may require an increased plot size.

Since guard rows often have to be included, the plot size should be sufficiently large to allow for net plots on which periodic sampling and evaluation of the crop yield at harvest can be carried out.

4.1.6 Number of replications

The number of replications to be included in one trial is dependent on the following factors:

(1) the likely magnitude of experimental variance;

(2) the number of treatments. (The fewer the treatments, the more replications are needed to give an acceptable estimate of variance.

In most cases 4-5 replications should be sufficient to give a reasonable estimate of the variation, but in special circumstances 3 may be acceptable.

An erratic distribution of the pests, diseases or weeds over the experimental area will call for a greater number of replications. In trials on glasshouse crops, if separate glasshouses or compartments have to be used (see Section 4.1.1.2) replications may be reduced to three or replaced by replications in time.

When crop yields are to be evaluated, replications should be sufficient in number and the plot size large enough to offset the variability in crop yield due to variation of soil or other environmental factors over the test area.

In the development stage of a pesticide, manufacturers often carry out a considerable number of trials with a simpler design for demonstration purposes (often unreplicated and without, or with only a small, non-treated control area). Data obtained in such trials may provide valuable additional information for the authorizing agency, but these trials cannot replace specific efficacy evaluation trials.

4.1.7 Application of the pesticides

The equipment used should give an even distribution of the pesticide product over the plot. The type of equipment used, which

should, where possible, be similar to that currently used in practice, should be recorded; when relevant, information should also be provided on operating conditions (e.g. type of nozzles, operating pressure in kPa), as well as any deviations in dosage of more than 10 percent.

The type, time and dosage of the pesticide application will generally be as proposed by the applicant. Precautions should be taken to ensure a minimum of interference with other pesticide applications.

4.1.8 Meteorological data

In the field, weather conditions around the time of application, precipitation (type and daily amount in mm), temperature (daily average, maximum and minimum in C degrees) should be recorded on the trial site or obtained from a nearby meteorological station. Extreme weather conditions such as severe and prolonged drought, storms, hail, etc., which are likely to influence the effect of the product(s) to be tested should also be recorded. For trials on glasshouse crops, temperature and humidity should be recorded throughout the trial period.

4.1.9 Assessment of efficacy

Observations should be scored using convenient qualifying methods such as the quantity and quality of yield, percent of control and extent of remaining pest populations, according to the pesticide and pest concerned.

For many pests and diseases, guidelines already exist specifying the type and times of assessments, the minimum sample sizes, sampling methods and the most suitable scoring systems. In any case the mode of assessment should be clearly stated.

4.1.10 Assessment of phytotoxicity and other side effects

The type and extent of phytotoxicity should be described and, where appropriate, recorded according to a recognized scale. Any detrimental effects on wildlife and/or beneficial organisms should also be recorded.

4.1.11 Statistical analysis of data

The raw data should be supplied (or held by the applicant for submission on request) and statistically analyzed where appropriate. The statistical method(s) used should be indicated.

4.2 Report of the Experiment

4.2.1 General remarks

The report section of the efficacy evaluation dossier is a very important but often rather neglected part of the presentation. This may be due to the circumstances that efficacy trials are often designed and carried out within the manufacturer's organization by skilled experts on a routine basis. A presentation of assessment data in a summarized form without explanation or clarification of specific methods of assessment will often suffice for the team of experimenters and others within the firm concerned with the efficacy evaluation. For their purposes headings of table may be left incomplete, since assessments are often carried out in a standard manner.

It should be recognized however, that such presentation of data is not suitable when these have to be provided to the authorizing agency or other interested parties. Although in many cases efficacy trials are carried out and assessments made according to high standards, the

presentation of data without sufficient details or clarification may give rise to loss of essential or valuable information for the expert(s) in the authorizing agency engaged with the evaluation of efficacy data of the pesticide for which a marketing authorization is sought.

Therefore, the importance of a suitable and sufficiently detailed presentation of data should be stressed.

In essence this means that all data obtained from the analysis of single samples should be recorded and not merely a summary or an average figure. If necessary, explanatory notes for erratic results should be provided. It should always be clearly stated how samples were taken and in which manner assessments were made. It is also essential that the evaluation method used to establish the effectiveness is described together with the way in which the results are interpreted.

4.2.2 Lay-out of the Report

It is essential that the presentation of the results should be standardized in order to facilitate understanding of the trial results. Therefore, the data should preferably be presented in the following way:

- name of the experimenter and organization responsible for the trial;
- objective and location of the trial;
- chemical name and formulation;
- pest, disease or weed against which tested;
- crops and cultivars;
- plant growth stage;
- soil type;
- experimental design, size and number of plots treated;
- application dates and rates;
- application method and equipment;
- volume of spray liquid or other carrier (types);
- weather conditions during and after treatment;
- treatment of the plots with other crop protecting materials, fertilizers and other products;
- application dates;
- dates of assessment;
- size and frequency of sampling;
- quantity and quality of the yield of the harvested crop;
- any results on crop safety including intervals to be observed in order to avoid phytotoxic effects;
- data assessment including significance;
- interpretation and discussion on the results of the experiment in comparison with similar trials.

REFERENCES

I. General

1. Report of the FAO ad hoc Government Consultation on International Standardization of Pesticide Registration Requirements (Rome, 24-28 October 1977). In particular: Committee 2, Assessment on biological activity, efficacy and crop safety and Resolution II, pp. 8-12.

2. Report of the EPPO Colloquium on Harmonization of Pesticide Efficacy Evaluation (Wageningen (NL), 16-17 February 1982). EPPO Bulletin 12(3): pp. 229-295.

3. Report of the Second FAO Government Consultation on International Harmonization of Pesticide Registration Requirements (Rome, 11-15 October 1982). In particular: Committee 1, Harmonization of data requirements - section 1.2, Assessment of efficacy of pesticides, pp. 7-9.

4. "Pesticides" 6th edition, 1984. Council of Europe, Strasbourg (FRG). In particular: Chapter VII, Guidance on efficacy data, pp. 66-73.

5. Unterstenhoefer, G. (1976). Die Grundlagen des Pflanzenschuytzfreilandversuch. Pflanzensschutz-Nachrichten Bayer, 29 (2): pp. 83-182.

6. Manual for field trials in plant protection. Documenta, Ciba-Geigy. 2nd edition (1981).

II. Specific Methods

7. EPPO Guidelines for the Biological Evaluation of Pesticides. European and Mediterranean Protection Organization (1975-1983). See Appendix II for details.

8. Guidelines for Field Evaluation of Herbicides. Pesticides Section, Dept. of Primary Industry, Canberra (Australia).

9. Méthodes d'essais élaborées et publiées par la Commission des Essais Biologiques (CEB), Société francaise de phytiatrie et de phytopharmacie, CNRA, Versailles (France).

10. Richtlinien fuer die amtliche Pruefung von Pflanzenschutzmitteln. Biologische Bundesanstalt (BBA), Braunschweig (FRG).

11. Methods for evaluating plant fungicides, nematicides and bactericides. American Phytopathological Society, St. Paul, Minnesota (1978).

12. Manual of biological testing methods for pesticides and devices. U.S. Environmental Protection Agency, Beltsville (Md.).

APPENDIX I

NEED FOR INTERNATIONAL HARMONIZATION IN EFFICACY EVALUATION PROCEDURES AND METHODS

1. Conclusions of the FAO ad hoc Government Consultation on International Standardization of Pesticide Registration Requirements (Rome, 1977)

The 1977 ad hoc Consultation recognized (1) that the requirements for the data base for efficacy evaluation and the methods of conducting, reporting and evaluating the results of field trials for efficacy evaluation vary from country to country. These differences in attitude toward the extent and type of information required for efficacy evaluation by the competent authorities give rise to duplication of laborious and often expensive field trial programmes. Due to this, the availability of useful pesticides may be hampered in various countries, whereas the cost price of the pesticide product for the user will sometimes be unnecessarily increased. Nowadays, there are very few countries which operate pesticide authorization or registration schemes and do not require data from a specific efficacy testing programme carried out to support the request for authorization to market the pesticide product in the country concerned.

In some countries, an efficacy evaluation forms a part of the authorization procedure, but this evaluation is exclusively based on manufacturers' efficacy trial data provided to the agency. In contrast to the latter procedure, some countries initially use the dossier on efficacy evaluation provided by the manufacturers only to judge if an efficacy testing programme, to be carried out by or on behalf of the agency, is required. The latter procedure especially does not take sufficiently into account the information already available from areas with similar ecological conditions and agricultural practices, and will give rise to duplication with the disadvantages mentioned earlier.

In light of all the differences in procedures and strategies between various countries with respect to efficacy evaluation in the framework of official authorization or registration of pesticides, the need for internationally acceptable harmonized procedures and test methods is obvious. The 1977 ad hoc Consultation (1) strongly stressed this unsatisfactory situation. In Resolution II, recommendations were given to improve the situation, together with specific advice for such improvements. The 1977 ad hoc Consultation agreed that:

> "International acceptance of methods designed to generate basic data on efficacy/crop safety to be used in support of registration would enable the data so generated in one country to be used as support or back-up for trials in other countries with similar agricultural regimes. Use of data in this way should be encouraged; for example: trials data regarding the effect of a certain pesticide on red mite control on apples would, provided that certain acceptable standards are met, be transportable to other countries in which apples are affected by the same species and should be suitable for consideration by the authorities there. Only limited trials to determine efficacy and crop safety would need to be done in other countries in which registration is sought, once good sound data have been developed elsewhere. Thus for the registration of a new pesticide in a particular country, fewer efficacy/crop safety tests might be needed if the results from other countries in which the product had already been registered were forthcoming, provided the original trials have been conducted in accordance with an approved international standard".

Note: Numbers in ( ) refer to references listed on page 9.

The ad hoc Consultation (1) recommended that:

(a) "fewer efficacy tests should be required for pesticides already registered in another country, for the same uses in similar agricultural and ecological conditions";

(b) "fewer efficacy tests should also be necessary for pesticides already registered for use against a particular pest or type of pest on some main crop in a country, when registration is required for similar use on additional crops";

(c) "fewer efficacy tests, if any, should be required for pesticides already registered, for which there are minor changes in formulation, and in these instances laboratory bio-assay tests, in comparison with a standard may be sufficient".

and that:

(d) "registration authorities should be prepared to consider data obtained under comparable conditions from field trials in any country, provided that these data are generated using recognized test methods and that reasonable scientific standards are met".

The need to develop convenient, suitably harmonized methods for testing pesticides with respect to efficacy in various crop (or livestock) pest situations has been expressed on many occasions and in several international bodies dealing with pesticide problems. The 1977 ad hoc Consultation endorsed this view strongly and recommended:

(e) "that every effort be made by FAO to encourage the development of test methods (particularly methods for use in tropical areas where such methods do not generally exist) suitable for generating data on efficacy/crop or livestock safety which can be used by regulatory authorities to determine whether the product is effective in the control of the pest and is safe to the crop".

It is obvious that the same methods should also be used by the manufacturers or other interested parties for providing relevant efficacy and crop safety data when an authorization for marketing the pesticide is sought.

2. EPPO Colloquium on the Harmonization of Pesticide Efficacy Evaluation (Wageningen, 1982)

The Colloquium organized by EPPO (European Mediterranean Plant Protection Organization) on the Harmonization of Pesticide Efficacy Evaluation, held in Wageningen, The Netherlands (16-17 February 1982) arrived at similar conclusions (2):

(a) The biological evaluation of a pesticide under practical use conditions (understood to cover its efficacy and crop safety) should form an integral part of the registration process for a pesticide. This evaluation should be made according to recognized criteria and by internationally accepted methods. These should preferably be taken into account in any experimentation on pesticide efficacy, in order to ensure maximum effort from the data obtained.

(b) International recognition of harmonized methods for biological evaluation of pesticides will facilitate the tasks of both national authorities and pesticide manufacturers and ensure that pesticides which are effective and safe to crops can be marketed and used without unnecessary expenditure of limited resources. The use of such methods (in particular, the EPPO guidelines for the biological evaluation of pesticides) should be specifically recommended at national level both to

1001
COMMUNITY HEALTH CELL
47/1, Third Floor, St. Marks Road,

authorities and to industry. The acceptability of these methods, and the degree of their equivalence to national methods, should be explicitly recognized. EPPO should continue to produce and update guidelines for this purpose, on the basis of experience of their practical use, which should be reported to the Organization.

(c) Authorities in individual countries should take into consideration relevant biological evaluation data obtained by such recognized methods in other countries, and provision should be made for this in registration procedures. This is of particular interest for the registration of pesticides for minor uses. The implementation of all these measures requires a positive commitment by national authorities on the acceptability of relevant data from other countries, produced by harmonized methods.

(d) With a view to developing international harmonization of biological evaluation beyond Europe and the EPPO region, methods from different parts of the world should be compared with the aim of arriving at least at a common framework for guidelines at world level. A collaborative international board, supported by FAO, EPPO and other international organizations, could be envisaged for this purpose. In the longer term, such a board could assess biological evaluation data at an international level, and provide a basis for pesticide registration decisions in developing countries in particular.

(e) The establishment of new or revised national regulations on biological evaluations for registration should take full account of international recommendations in this field.

In September 1983, the EPPO Council formally adopted these conclusions as recommendations to its member countries.

3. Second FAO Government Consultation on International Harmonization of Pesticide Registration Requirements (Rome, 1982)

The Second Consultation (3) reviewed progress in the development of harmonized procedures and methods and in their acceptance and use of registration authorities. It noted in particular that:

"Substantial progress in harmonized methods has been made since 1977. In particular, the European and Mediterranean Plant Protection Organization (EPPO), taking as its basis nationally harmonized methods submitted by its member countries, has now drawn up 37 internationally agreed harmonized Guidelines for the Biological Evaluation of Pesticides for the control of particular pests and diseases (7). Regular publication of new guidelines can be expected. The work of a joint panel involving specialists from EPPO and the European Weed Research Society (EWRS) should shortly result in publication of Guidelines for the Biological Evaluation of Herbicides. All EPPO guidelines follow a unified framework.

"Attention should also be drawn to activities in the field of national harmonization of efficacy evaluation methods, particularly those of the American Society for Testing and Materials (ASTM), the American Phytopathological Society (APS)(11), and the Australian Weed Committee (8). The harmonized methods developed by these national agencies can form the basis for the elaboration of internationally harmonized guidelines. Finally, attention should be drawn to the Council of Europe's publication 'Pesticides', 5th Edition (4), which provides a valuable general background of recommendations for the conduct of an efficacy trials programme, set in the broader context of the whole registration procedure.

"In spite of the considerable progress which has been made, there are still areas where harmonized efficacy evaluation guidelines are lacking. In particular, there is an urgent need for methods on pesticides applied against the pests, diseases and weeds of the major tropical and sub-tropical crops. Developments in this field could, with advantage, be modelled on the activities referred to above. A common framework for guidelines should be established and regional organizations and institutions and institutes in the tropical and sub-tropical zones should be encouraged to identify the priorities for harmonized guidelines and to undertake a programme for their preparation in consultation, where appropriate, with agencies already working in the field. Harmonized methods are also lacking for the evaluation of pesticides used in animal husbandry and consideration needs to be given to the most suitable way of encouraging progress in this field, recognizing the different authorities which deal with the problem at national and international levels."

The Consultation stressed particularly the need for commitment from national authorities to recognize particular harmonized methods and to accept data obtained by their use. It recommended, in particular, with reference to the preparation of harmonized methods, that:

(a) The FAO document 1/ is of sufficient importance that FAO bring it to the immediate attention of governments and subsequently publish it as approved FAO Guidelines;

(b) FAO should take action which leads to the promotion, adoption and employment of the specific EPPO Guidelines for Biological Evaluation of Pesticides (7);

(c) EPPO and other agencies developing guidelines should be encouraged to continue their activities in this field;

(d) in so doing, methods from different parts of the world should be compared with the aim of arriving at least at a common framework for guidelines at world level;

(e) FAO should encourage appropriate regional organizations and institutes to establish programmes for the preparation of guidelines for the efficacy evaluation of pesticides for the control of pests, diseases and weeds of major tropical/sub-tropical crops;

(f) consideration should be given to preparation of harmonized methods for efficacy evaluation of pesticides used in animal husbandry;

and, with reference to implementation of their use, that:

(g) efficacy evaluation should be based primarily on the data provided by the applicant, using harmonized methods and reported in a systematically presented complete dossier;

(h) registration authorities should positively commit themselves to the recognition of particular internationally harmonized methods (such as the EPPO Guidelines for Biological Evaluation of Pesticides (7) and to the acceptability of relevant efficacy evaluation data, produced by such methods, in other countries or regions, or from other competent sources;

(i) where resources permit, the registration authority should participate in at least a proportion of the trials carried out by the applicant and, if deemed necessary, organize limited additional efficacy trials.

1/ FAO Guidelines on Efficacy Data for the Registration of Pesticides, prepared by the Group on Registration Requirements of the FAO Panel of Experts on Pesticide Specifications, Registration Requirements and Application Standards, presented to the Consultation as Background Paper 6, and serving as the direct basis for the present guidelines.

APPENDIX II

EPPO GUIDELINES FOR THE BIOLOGICAL EVALUATION OF PESTICIDES

SET 1 (1979)

1. *Cercospora beticola*
2. *Phytophthora infestans*
3. *Pseudoperonospora humuli*
4. *Uncinula necator*
5. *Venturia inaequalis* & *V. pirina* (protectants)
6. *Adoxophyes orana*
7. *Cydia pomonella*
8. *Delia antiqua*
9. *Delia brassicae*
10. *Delia coarctata*
11. *Eurpoecilia ambiquella* & *Lobesia botrana*
12. *Leptinotarsa decemlineata*
13. *Ostrinia nubilalis*
14. *Psila rosae*
15. Red Spider Mites in Orchards

SET 2 (1980)

16. *Botrytis cinerea* on Strawberries
17. *Botrytis cinerea* in Vineyards
18. Storage Rot and Storage Scab on Apples
19. Seed-borne Cereal Fungi
20. Aphids on Cereals
21. Aphids on Fruit
22. Aphids on Hops
23. Aphids on Ornamental Plants
24. Aphids on Potato, Sugar Beet, Pea, Broad Bean and other Vegetables
25. *Globodera* & *Heterodera* spp.

SET 3 (1981)

26. *Erysiphe graminis*
27. Cereal Rusts
28. *Pseudocercosporella herpotrichoides*
29. *Septoria* on Wheat
30. *Blumeriella jaapii*
31. *Plasmopara viticola*
32. *Rhizoctonia solani*
33. *Hoplocampa* spp.
34. *Phorbia platura* & *P. florilega*
35. *Rhagoletis cerasi*
36. *Trialeurodes vaporariorum*
37. *Tetranychus urticae*

SET 4 (1982)

38. Monilia laxa
39. Plasmodiophora brassicae
40. Soil Fungi Attacking Ornamental Plants
41. Stigmina carpophila
42. Venturia inaequalis & V. pirina (curative treatments)
43. Atomaria linearis
44. Psylla spp. on Pears
45. Scutigerella immaculata
46. Wireworms
47. Ditylenchus dipsaci
48. Migratory Root Nematodes

SET 5 (1983)

49. Weeds in Brassica Oil Crops
50. Weeds in Maize
51. Weeds in Potato
52. Weeds in Sugar and Fodder Beet
53. Weeds in Vicia Beans
54. Botrytis spp. on Vegetables
55. Phomopsis viticola
56. Phytophthora spp. on Citrus
57. Powdery Mildew of Cucurbits
58. Agrotis segetum
59. Noctuids in Vineyards
60. Sitona lineatus

SET 6 (1984)

61. Weeds in Grassland
62. Weeds in Paddy Rice
63. Weeds in Sunflower
64. Weeds in Vineyards
65. Bremia lactucae
66. Fungal storage rots of potatoes
67. Gloeosporium olivarum
68. Peronospora tabacina
69. Podosphaera leucotricha
70. Aphid vectors of barley yellow dwarf virus
71. Aphid vectors of leaf roll virus on seed potatoes
72. Planococcus citri
73. Psylliodes chrysocephala
74. Scales on citrus

SET 7 (1985)
Contact EPPO, 1, rue le Nôtre, 75016 Paris for details of these.

GUIDELINES FOR THE BIOLOGICAL EVALUATION OF RODENTICIDES (1982)

No. 1 - Laboratory Tests for Evaluation of the Toxicity and Acceptability of Rodenticides.

No. 2 - Field Tests against synanthropic Rodents (Mus musculus, Rattus norvegicus, R. rattus)

M/R5024/E/10.86/2/2000